

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

FAYE GORE, Individually and Executrix of
the ESTATE OF WADE MILLER GORE,
Deceased,

Plaintiff,

v.

3M COMPANY a/k/a MINNESOTA MINING
AND MANUFACTURING COMPANY,
et al.,

Defendants.

File No. 5:16-CV-716-BR

**PROTECTIVE ORDER GOVERNING
RELEASE OF PATHOLOGY MATERIALS**

THIS MATTER came before the Court upon Duke University Health System, Inc.'s (hereinafter "DUHS") Motion for Protective Order Governing Release of Pathology Materials following Defendant John Crane, Inc.'s (hereinafter "Defendant John Crane") request to DUHS and Motion for the release of original pathology material. Upon review of the file and motion, it appears to the Court as follows:

1. This matter arises out of Plaintiff's allegation of occupational disease allegedly caused by exposure to asbestos.
2. On October 21, 2015, specimen was obtained from Wade Miller Gore ("Mr. Gore") while a patient at DUHS. Dr. Thomas A. Sporn, a DUHS pathologist, issued a surgical pathology report (Accession SP15-033526) dated November 15, 2015 regarding the specimen.
3. On November 4, 2015, specimen was collected again from Mr. Gore while

a patient at DUHS. Dr. Sporn issued a surgical pathology report (Accession SP15-035277) dated November 6, 2015 regarding the specimen.

4. On or about April 12, 2017, DUHS received a request from counsel for Defendant John Crane for the release of the following original tissue blocks: Blocks C1-C3 and Block D1 from Accession SP15-033526 and Block A1 from Accession SP15-035277.

5. On receipt of Defendant John Crane's request for original pathology material in April 2017, counsel for DUHS informed both parties of DUHS's mandate to retain original pathology slides, tissue blocks, and wet tissue pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and College of American Pathologists (CAP).

6. In moving for a protective order regarding the release of the requested pathology materials, DUHS, a non-party to this claim, contends that federal regulations, accreditation requirements, and North Carolina Session Law 2013-14 (previously N.C. Senate Bill 240) govern the amount of time that laboratories are required to retain and preserve original pathology materials, and the manner in which original pathology materials may be released. Specifically, federal regulations under CLIA 88 mandate that DUHS retain original tissue blocks for two years from the date of collection. In addition, CAP standards mandate that DUHS retain original tissue blocks for ten years from the date of collection. Failure to comply with these regulations and requirements may subject DUHS to sanctions, loss of accreditation, and/or loss of Medicare reimbursement.

7. DUHS acknowledges, however, the pendency of the present litigation and Defendant John Crane's request to perform destructive, fiber analysis testing on tissue contained in the pathology blocks. Defendant John Crane contends that fiber analysis testing of the requested pathology blocks may demonstrate the liability and/or non-liability of some or

all of defendants.

8. In an effort to resolve this matter without further court intervention, DUHS will release the tissue blocks requested by Defendant John Crane, specifically Blocks C1-C3 and Block D1 from Accession SP15-033526 and Block A1 from Accession SP15-035277, to the Defendant John Crane, care of Susan Brooks at O'Connell, Tivin, Miller and Burns, LLC, 400 E. Wisconsin Avenue, Suite 400, Milwaukee, WI 53202, (414) 455-8709, sbrooks@otmblaw.com, for fiber analysis testing in accordance with the terms of the *Protective Order Governing Release of Pathology Materials*. The proposed order is necessary to prevent an undue burden that exists given the federal regulations, accreditation requirements, and other North Carolina legislation governing the retention, preservation, and release of original pathology materials as described above.

9. Furthermore, any unused portions of the tissue blocks shall be returned to DUHS for compliance with the CLIA 88 and CAP regulatory requirements and standards.

10. By entry of this Order, DUHS does not waive any objections that may be asserted should additional pathology material be requested in the future, and that this Order relates to and governs the release solely of those pathology materials requested by Defendant John Crane and identified above.

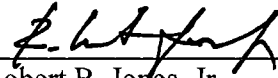
IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that:

1. Upon completion of proper authorization for release of pathology materials, DUHS will release tissue pathology Blocks C1-C3 and Block D1 from Accession SP15-033526 and Block A1 from Accession SP15-035277.
2. Upon delivery of the released tissue, the parties shall handle, preserve and transport the released tissue pursuant to any and all state and federal regulations and laws and

applicable protocols.

3. If the released original pathology material is subsequently broken or lost, DUHS shall be operating, for purposes of CLIA 88 and CAP, under the protection of this Court's Order.
4. Fiber analysis testing may be performed by Defendant John Crane's expert witness(es) on the requested tissue blocks in an amount necessary to perform such testing.
5. Upon completion of the testing, any unused portions of the tissue blocks released to the Defendant John Crane shall be returned to DUHS for compliance with CLIA 88 and CAP.
6. DUHS shall retain all original histopathology slides and all other paraffin tissue blocks containing specimen collected from Wade Miller Gore while a patient at DUHS.

SO ORDERED, the 2 of November 2017.



Robert B. Jones, Jr.
United States Magistrate Judge